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TO: US Patent & Trademark Office
Examiner R. Shukla
Group Art Unit 1632

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DATE: November 21, 2001

PAGES (WITH COVER SHEET): 3

FROM: David L. Bernstein
ARIAD Pharmaceuticals, Inc.
26 Landsdowne Street
Cambridge, MA 02139

DIRECT FACSIMILE NO.: 617-494-0208
TELEPHONE NO.: 617-494-0400

FACSIMILE MESSAGE

Attached please find an Amendment, Response and Petition for a Five-Month Extension of Time.

Application Number	: 09/407,402
Filing Date	: September 28, 1999
Group Art Unit	: 1632
Applicant	: Natesan & Gilman
Title	: Chimeric Transcription Factors

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In The United States Patent and Trademark Office

Applicant : Natesan & Gilman

USSN : **09/407,402**

Filed : 9/28/99

For : Chimeric Transcription Factors

Art Unit : 1632**Examiner : R. Shukla**Assistant Commissioner for Patents
Washington, DC 20231

November 21, 2001

Amendment, Response and Petition for 5-Month Extension for Response

This is in response to the 5/22/01 Office Action, a response to which was originally due on 6/22/01. Applicants hereby petition for a five-month extension of time and authorize the PTO to charge our Deposit Account 01-2315 the required \$980.00 fee, as well as to charge any other fee which may be due at this time in connection with this matter, and credit any overpayment, to that Deposit Account. Accordingly, this Response should be considered timely filed.

Response to Restriction Requirement with Traversal

Pending claims 1 – 67 have been restricted to the following three groups:

- Claims 1 – 43, 45-48, 57-59 and 65-67 drawn to ex vivo transduction methods,
- Claims 1 – 42, 44-48, 57-59 and 65-67 drawn to in vivo transduction methods, and
- Claims 1 – 5, 31, 45, 49 - 56 and 60-64 drawn to non-human organisms.

We find this confusing since the division of claims and their designations are inconsistent with the structure, class and explicit language of the claims and do not encompass all of the claimed subject matter in this case. For instance, in accordance with the restriction requirement, applicants could elect to examine ex vivo or in vitro transduction methods as defined by claims 1-38 (et al). However, those claims are drawn to *compositions of matter*—not methods. Faced with a restriction requirement, we would wish to elect at the least the recombinant nucleic acids of claim 1 – 38. Unfortunately, that crucial subject matter is not one of the apparent choices in the instant restriction. We request that the restriction requirement be reconsidered and withdrawn or recast in view of the foregoing and the additional remarks which follow.

Inventory of claims

- Claims 1 – 38, drawn to recombinant nucleic acids and vectors, viruses & compositions containing them,
- Claims 39 – 44, drawn to methods for genetically engineering cells (of which claim 43 specifies in vitro and claim 44 specifies in vivo),
- Claims 45 – 51, drawn to cells containing specified recombinant nucleic acids,
- Claims 52 and 53, drawn to non-human organisms containing specified cells,
- Claims 54 – 59, drawn to methods for rendering an organisms capable of regulated gene expression
- Claims 60 – 67, drawn to methods for stimulating transcription of a target gene in cells or organisms.

If, upon reconsideration, restriction of this case is still thought to be appropriate, applicants respectfully request a restriction in which the various groups include between them *all* of the claimed subject matter of the pending claims (including e.g. claims to recombinant nucleic acids), together with a statement of

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the legal basis for such restriction. Under the circumstances and mindful of conventional PTO practices, applicants respectfully request keeping together, at the least, the claimed recombinant nucleic acids, various compositions containing them and methods for using them (e.g., claims 1 - 59).

Applicants also address a number of positions put forth in the Office Action:

In Point #3, claims 1-5, 31 and 45 were said to be multiple dependent claims. Of those claims, only claim 45 is actually a multiple dependent claim.

In point #5, the following were said to be patentably distinct species of the claimed invention: a transcription potentiation domain, a DNA binding domain, tetR repressor domain and a stabilization domain. Those items are more accurately called claim elements representing components of the various species of the claimed invention rather than species themselves. Thus, one species of the invention could contain a number of those items (simultaneously). For instance, one species could involve a recombinant nucleic acid encoding a chimeric transcription factor containing a DNA binding domain, a transcription potentiating domain, a domain derived from tetR and a stabilization domain. Accordingly, because those elements are *not* independent species, the fact that each of those elements may have acquired a separate status in the art and may require a separate search is not relevant to restriction practice and does not make restriction or election of one of them necessary or proper under current PTO practice.

While applicants hope that the restriction requirement is reconsidered and withdrawn or redrafted, and actually wish to elect claims to recombinant nucleic acids of claims 1 - 38 at the minimum, in the interest of making a complete response, applicants provisionally elect Group II and elect the species involving a recombinant nucleic acid encoding a chimeric transcription factor comprising a p65 transcription activation domain, a DNA binding domain and a hormone receptor (e.g. a progesterone receptor). However, in the event that the restriction requirement is redrafted, applicants reserve the right to make a different election consistent with those changed circumstances.

In conclusion, applicants consider the restriction requirement to be improper for the foregoing reasons and hope that the examiner agrees, upon reconsideration of our claims. Applicants do look forward to resolving these and subsequent issues with the Examiner during the prosecution of this important case. If it might be helpful in answering any questions or otherwise advancing prosecution, applicants earnestly invite the Examiner to call their attorney at the number provided below.

Respectfully submitted,

David L. Berstein

David L. Berstein, Reg. No. 31,235
ARIAD Gene Therapeutics, Inc.
26 Landsdowne Street
Cambridge, MA 02139
(617) 494-0400 Ext. 266

I hereby certify that this paper is being sent by telefax on the date indicated below to the US PTO Group fax number provided by the Examiner: (703) 308-4242.

date: 11/21/01

Sue Wilson
Sue Wilson